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Andre R. Abad

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

1. Claims 1-3, 9-12, 17-19, 38, 43, 46, 49, 52 and 55-64 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1-3, 9-12, 17-19, 38, 43, 46, 49, 52 and 55-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels et al (1996, US Patent 5,554,534). The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 April 2008. Applicant's arguments filed 11 July 2008 have been fully considered but they are not persuasive.

The claims are drawn to nucleic acids with at least 90%, 93%, 94% or 95% identity to SEQ ID NO:1, wherein the nucleic acid encodes a protein with pesticidal activity for a pest of the order Coleoptera, including western corn rootworm, southern corn rootworm, Colorado potato beetle, and boll weevil. The claims are also drawn to plants, including maize and dicots, transformed with the nucleic acid and methods comprising transforming a plant with a construct comprising the nucleic acid operably linked to a plant promoter.

Michaels et al teach a nucleic acid with 85.1% identity to SEQ ID NO:1 (see search results); the nucleic acid encodes a protein with pesticidal activity toward the Coleopterans *Cyclocephala pasadenae*, *C. borealis* and *Popillia japonica*. The protein has 79.8% identity to the instant SEQ ID NO:2, the protein encoded by the instant SEQ ID NO:1 (see search results). Michaels et al also teach plants transformed with constructs comprising the nucleic acid and a

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method of using it to impact a plant pest (column 15, line 5, to column 16, line 35). Michaels et al do not teach nucleic acids with at least 90%, 93%, 94% or 95% identity to SEQ ID NO:1.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the nucleic acid taught by Michaels et al to produce nucleic acids with at least 90%, 93%, 94% or 95% identity to the instant SEQ ID NO:1. One of ordinary skill in the art would have been motivated to do so because Michaels et al suggest making variant toxins with 75% homology to their protein (column 6, lines 26-67). These toxins would include those that are encoded by nucleic acids with at least 90%, 93%, 94% or 95% identity to the instant SEQ ID NO:1, given the sequence identity between the instant SEQ ID NO:1 and the nucleic acid taught by Michaels et al and the sequence identity between the instant SEQ ID NO:2 and the protein taught by Michaels et al. Further, one of ordinary skill in the art would have been motivated to make these toxins where they are pesticidal to western corn rootworm, southern corn rootworm, Colorado potato beetle, or boll weevil, given the economic impact of these pests on major crops like potato, corn and cotton. One of ordinary skill in the art would have been motivated to transform maize, potato and/or cotton with constructs comprising the variant nucleic acids operably linked to a plant promoter, to thus produce plants that have resistance to these pests. One of ordinary skill in the art would have been motivated to produce seeds from the corn and cotton plants, as this is how these plants, and many other crops, are sold to farmers. One of ordinary skill in the art would have been motivated to optimize expression of the nucleic acids for expression in a plant to get higher expression levels of the pesticidal protein in the plants.

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Applicant urges that in contrast to *Kubin*, the art was not in possession of a monoclonal antibody that can be used to isolate a protein encoded by the claimed sequences (response pg 3).

This is not found persuasive because a monoclonal antibody would not be required to make nucleic acids encoding variants of the protein taught by Michaels. All that would be required is knowledge of the structure of Cry endotoxins and of how to make amino acid and nucleotide substitutions. Both of these are well-established in the art. See the BPAI decision of 3 April 2008.

Applicant urges that '534 does not contain a prophetic example teaching how to isolate one of the claimed sequence, nor does it teach the isolation or construction of a sequence within the scope of the claims (response pg 3).

This is not found persuasive because all that would be required are methods routine in the molecular biology art, including those for making mutations.

Conclusion

4. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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October 25, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638